REMARKS/ARGUMENTS

Claims 61-68 and 79-85 were examined and rejected. Claims 1-60 and 69-78 have been previously cancelled.

Applicants amend claim 61-63, 66 and 84; and cancel claim 85. Applicants submit that no new matter is added herein. Without limitation thereto, amendments to the claims are supported at least at paragraphs 439-444 and Figs. 82-89 of the application; and prior claim 85. The amendments are supported, for example, at paragraphs 442 and 443 which describe that a balloon may be deflated or a lumen extending through the canula may be used to allow a flow of fluid, such as blood, to reflow through the region of interest, by allowing blood to flow from a location proximal to the balloon to a location distal to the balloon, to perfuse blood and the treatment agent from the region of interest distal to the balloon (e.g., deflate occlusion balloon 8810 of Fig. 85, or use blood flow 9682 of Fig. 85 which flows through lumen 9530 to perfuse blood and the treatment agent at region of interest 996). The amendments are also supported, for example, at FIG. 82 block 9675 and corresponding paragraph 442 of the application, which describe "liquid (e.g., such as blood and/or a treatment agent) is allowed to perfuse from a location in the blood vessel proximal to the balloon to the region of interest" (e.g., see region of interest 996 distal to balloon 8810 as described at paragraph 439 and fig. 85).

Applicants respectfully request reconsideration of claims 61-68 and claims 79-84 in view of the following remarks.

I. Claim Rejections – 35 U.S.C. § 103

Claims 61-66, 68 and 79-85 are rejected under 35 U.S.C. § 103(a) as being unpatentable over US Patent Publication No. 2002/0049402 to Peacock ("Peacock").

Applicants respectfully disagree with the rejection above for at least the reason that the cited reference does not teach inflating the balloon from a first diameter to a different second diameter that is at least equivalent to an inner diameter of a blood vessel to occlude the blood vessel at the region of interest wherein inflating includes inflating the balloon for a first period of time to occlude the blood vessel for the first period of time; then infusing a treatment agent to the region of interest distal to the balloon during the occlusion of the blood vessel; then perfusing blood and the treatment agent wherein perfusing comprises allowing blood to flow from a

location in the blood vessel proximal to the balloon to the region of interest distal to the balloon, wherein perfusing comprises perfusing immediately after the first period of time, as required by claim 61.

Peacock paragraph 71 describes that when valve (6) is open and valve (7) is closed, antegrade aortic blood flow is shunted into distal flow port (4), through the internal flow lumen, out intermediate flow port (5), and into a proximal region of the aorta located proximally of the external shunt valve (3). However, this does not teach perfusing blood and the treatmcnt agent wherein perfusing comprises allowing blood to flow from a location in the blood vessel proximal to the balloon to the region of interest distal to the balloon, as required by claim 61.

Next, Peacock paragraph 73 describes that cardioplegia delivery port (8) is located distally of external shunt valve (3) in order to locally delivery the cardioplegia agent to the left heart and isolate the cardioplegia agent delivered from systemic circulation. Thus, Peacock paragraph 73 does not teach, perfusing blood and the treatment agent flow from a location in the blood vessel proximal to the balloon to the region of interest distal to the balloon wherein perfusing comprises perfusing immediately after the first period of time, as required by claim 61.

Moreover, there is no teaching in Peacock of combining the descriptions of paragraphs 71 and 73 as suggested in the rejection. Instead, Peacock teaches against such a combination by teaching that "the cardioplegia delivery port (8) is adapted to be positioned within the aortic root such that cardioplegia agent may be delivered to the heart via the coronary arteries stemming therefrom...so long as cardioplegic delivery port (8) is located distally of external shunt valve (3) in order to locally delivery the cardioplegia agent to the left heart and isolate the cardioplegia agent delivery from systemic circulation; and the ventricular venting port (9) is adapted to be positioned within the left ventricle...." (see paragraph 73). Thus, Peacock requires and cannot allow the treatment agent to flow from a location in the blood vessel proximal to the balloon to a region of interest distal the balloon as required by claim 61 because any treatment agent infused through port 8 or 9 will be clearly pushed by the heart from a location distal of valve 3 to a location proximal in the vessel from valve 3.

Moreover, it is noted that perfusing blood and the treatment agent, as required by claim 61 requires that the treatment agent that is infused is the same agent that is perfused, immediately after the period of time of inflating the balloon. However, the cited references do not teach such limitations.

On the other hand, for example, without limitation thereto, by perfusing blood and the treatment agent, wherein perfusing comprises allowing blood to flow from a location in the blood vessel proximal to the balloon to the region of interest distal to the balloon wherein perfusing comprises perfusing immediately after the first period of time embodiments described in the specification, for example, without limitation thereto provide the unexpected benefits of: (1) allowing drugs to be injected distal to the balloon without being washed away, and then allowing the blood and drugs to be perfused using the ports located distal and proximal to the balloon to allow blood flow and avoid ischemia (see at least para. 439 and 458 of the application; and claims 62 and 64); (2) so that the drugs can be injected, and the blood and drugs can be perfused repeatedly, with a simple process, while the balloon stays inflated (e.g., does not need to be deflated and reinflated) to occlude the blood vessel (see at least FIG. 82-85; paras. 445-447 and 461 of the application; and claims 63 and 65); (3) allowing the amount of blood and treatment agent perfused to be controlled over a desirable range, such as by retracting and extending a guide wire in a lumen (see at least FIG. 88; paras. 459-462 of the application; and claims 64 and 66); and (4) allowing the surgeon to balance the benefit of having a long treatment agent or progenitor cell residence time at the region of interest, with the risk of inducing ischemic damage to the targeted muscle during inclusion of the blood vessel (see at least paragraph 441 and Fig. 82 of the application). However, Peacock does not contemplate or enable such benefits.

Next, in addition to the dependence upon claim 61, Applicants respectfully disagree with the rejection of claim 63 for at least the reason that Peacock does not teach a method including at least one more repetition of inflating, infusing, and deflating as required by claim 63. Peacock only describes using valve (6) and valve (7) to shunt antegrade aortic blood flow into distal flow port (4); and locally delivery the cardioplegia agent to the left heart (see paragraphs 71-73). Thus, the Patent Office has not identified and Applicants are unable to identify any teachings in Peacock of the above noted limitations of claim 63. Hence, Applicants respectfully request the Patent Office withdraw the rejection of claim 63 for this additional reason.

Moreover, in addition to the dependence upon allowable base claim 61, Applicants respectfully disagree with the rejection of claim 64 for at least the reason that Peacock does not teach or enable retracting a guidewire from a location distal to at least on hole to a location proximal to the at least one hole to cause profusion through the at least one hole as required by

claim 64. However, the Patent Office has not identified and Applicants are unable to find any teaching or enablement of a guidewire of Peacock being retracted to cause profusion through at least one hole in the exterior surface of a canula as required by claim 64. Instead, Peacock only describes using valve (6) and valve (7) to shunt antegrade aortic blood flow into distal flow port (4); and locally delivery the cardioplegia agent to the left heart (see paragraphs 71-73). Hence, for at least this additional reason, Applicants respectfully request the Patent Office withdraw the rejection of claim 64.

Furthermore, in addition to its dependence upon allowable base claim 61, Applicants respectfully disagree with the rejection of claim 66 for at least the reason that Peacock does not teach or enable retracting a distal end of a guidewire to control an amount of a blood and treatment agent profusion, as required by claim 66. Peacock only describes using valve (6) and valve (7) to shunt antegrade aortic blood flow into distal flow port (4); and locally delivery the cardioplegia agent to the left heart (see paragraphs 71-73). Hence, for at least this additional reason, Applicants respectfully request that the Patent Office withdraw the rejection of claim 66.

Next, in addition to the dependence upon claim 61, Applicants respectfully disagree with the rejection of claim 83 for at least the reason that Peacock does not teach or enable retracting a distal end of a guidewire to a location proximal to at least one hole to allow profusion, as required by claim 83. An argument analogous to the one above for claim 64 applies here as well. Hence, for at least this additional reason, Applicants respectfully request withdrawal of the rejection above of claim 83.

Alt teaches using autologis adult stem cells which are derived from the same patient to replace necrotic tissue of a failing organ of that patient, such as a heart after an MI (see col. 5, line 52 through col. 6, line 32). However, the Patent Office has not identified and Applicants are unable to find any teaching in Alt of the above-noted limitations of the claims.

II. Dependent Claims

Any dependent claims not mentioned above are submitted as being patentable for at least the reasons provided in support of their base claim, as well as additional limitations of each dependent claim.

Hence, Applicants respectfully request the Patent Office withdraw all the rejections above.

CONCLUSION

In view of the foregoing, it is believed that all claims now pending patentably define the subject invention over the prior art of record, and are in condition for allowance and such action is earnestly solicited at the earliest possible date. If the Examiner believes a telephone conference would be useful in moving the case forward, he is encouraged to contact the undersigned at (310) 207-3800.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2666 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17, particularly extension of time fees.

Respectfully submitted,

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CERTIFICATE OF TRANSMISSION

I hereby certify that this correspondence is being submitted to the United States Patent and Trademark Office electronically via EFS Web on the date shown below.

Suzanne Johnston — 10/2/09 Date